

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

GENZYME CORPORATION,)	
<i>Plaintiff,</i>)	
)	
v.)	Civil Case No. JFM-09-563
)	JFM-09-1258
LUPIN LTD., et al.,)	JFM-10-1906
<i>Defendants.</i>)	
GENZYME CORPORATION,)	
<i>Plaintiff,</i>)	
)	
v.)	Civil Case No. JFM-09-653
)	JFM-09-846
IMPAX LABORATORIES, INC.)	JFM-10-1791
<i>Defendant.</i>)	
GENZYME CORPORATION,)	
<i>Plaintiff,</i>)	
)	
v.)	Civil Case No. JFM-09-1750
)	JFM-10-1715
SANDOZ, INC.)	
<i>Defendant.</i>)	
GENZYME CORPORATION,)	
<i>Plaintiff,</i>)	
)	
v.)	Civil Case No. JFM-09-2589
)	
ENDO PHARMACEUTICALS, INC.)	
<i>Defendant.</i>)	
)	

MEMORANDUM

Plaintiff Genzyme Corporation (“Genzyme”) has filed an action against defendants Endo Pharmaceuticals Inc., Impax Laboratories Inc., Sandoz Inc., Lupin Ltd., and Lupin

Pharmaceuticals Inc. (collectively, “Defendants”) for infringement of United States Patent No. 5,667,775 (“the ’775 Patent”). The ’775 Patent covers the therapeutic use of phosphate binding “amine polymers” in Genzyme’s FDA-approved RENAGEL® and RENVELA® pharmaceutical products. On January 21, 2011, the Court held a hearing to resolve a claim construction dispute centering on the patent claim term “amine polymer.” For the reasons that follow, I hold that the term “amine polymer” refers to a molecule composed of repeating structural units, one or more of which contains an amine group.

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff Genzyme is a drug manufacturer and the holder of the ’775 Patent, which relates to the therapeutic use of certain types of molecules, called “amine polymers,” to combat hyperphosphatemia, an excess of phosphorous in the body often occurring in individuals with impaired kidney function. Using the technology described in the ’775 Patent, Genzyme developed two drugs, RENAGEL® and RENVELA®, the active ingredient of which is sevelamer, a specific type of amine polymer. When administered to patients, the amine polymers in these drugs bind to phosphate in the body and, through a process called ion exchange,¹ effectively control phosphate levels in patients on dialysis suffering from chronic kidney disease. Defendants are drug manufacturers seeking to market generic versions of these products also utilizing the amine polymer sevelamer. Genzyme alleges that Defendants have infringed its ’775 Patent and filed this action in federal court. Pursuant to a December 1, 2009 Scheduling Order, the parties have submitted briefings to the Court to assist the interpretation of the disputed patent claim term “hydrophilic cross-linked aliphatic amine polymer.”

¹ According to Genzyme, “ion exchange” refers to “the exchange of an ion—a charged atom like chlorine (Cl⁻) or group of atoms—for another, like phosphate (PO₄³⁻).” Through this exchange process, excess phosphate is removed from the body.

Claim 22 of the '775 Patent, the only claim asserted by Genzyme in this case, reads as follows:

22. A method for removing phosphate from a patient by ion exchange, comprising orally administering to said patient a therapeutically effective amount of a composition comprising at least one hydrophilic cross-linked aliphatic amine polymer.

Although the parties largely agree about the meaning of the claim term, they dispute the construction of the phrase “amine polymer.” The parties agree that a “polymer” is a large molecule composed of repeating structural units (called “monomers”) that are connected by chemical bonds. A polymer can be composed of repeating units of a single type of monomer or repeating units of more than one type of monomer. When a polymer is composed of more than one type of monomer, it is referred to as a “copolymer.” The parties also agree that the word “amine” refers to a nitrogen-based organic compound derived from ammonia. (*See* '775 Patent, at 2:40-43.) In spite of their agreement about the individual words “amine” and “polymer,” the parties vigorously dispute the meaning of the phrase “amine polymer.” Genzyme construes “amine polymer” to mean a polymer in which *each and every* repeating unit contains an amine group. (Pl.’s Opening Br. at 1-2.) Defendants assert that “amine polymer” refers to a polymer in which *one or more*, but not necessarily all, repeating units contain an amine group. (Def.’s Opening Br. at 1.) The parties’ respective constructions of the disputed claim term are shown below:²

Disputed Claim Term	Genzyme’s Proposed Construction	Defendants’ Proposed Construction
“hydrophilic cross-linked aliphatic amine polymer”	A molecule that is capable of interacting with a polar	A molecule that is capable of interacting with a polar

² This case is somewhat unusual in that the patentee, Genzyme, argues for a narrower construction of the disputed claim term while the alleged infringers, Defendants, propose a broader construction. At oral argument, the parties explained that they had taken these positions in preparation for Defendants’ anticipated invalidity defense.

	solvent; is non-aromatic; contains cross-links; and contains one or more repeating units, <u>each of which contains an amine group.</u>	solvent; is non-aromatic; contains cross-links; and contains one or more repeating units, <u>one or more of which contains an amine group.</u>
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II. ANALYSIS

The construction of a patent claim is a purely legal question properly decided by a district court. *Markman v. Westview Instruments*, 517 U.S. 370, 391 (1996) [*Markman II*].

Occasionally, the resolution of a claim construction dispute “involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips v. AWH, Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). More often, however, the meaning of a disputed claim term is less obvious and requires a deeper inquiry. In *Phillips v. AWH, Corp.*, the Federal Circuit set forth an analytical framework for resolving such claim construction disputes. The *Phillips* court held that claim construction begins with and is largely determined by intrinsic evidence, including the claim language, the patent specification, and the prosecution history of the patent. *Id.* at 1314; *see also Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“[T]he court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and . . . the prosecution history.”). “[I]f further guidance is needed,” a district court can look to extrinsic evidence such as dictionary definitions and expert testimony. *Nazomi Commc’ns, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1369 (Fed. Cir. 2005).

A. **Claim Language**

The claim construction inquiry starts with the language of the claim itself, as “it is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure*

Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Claim terms are “generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Id.* at 1312-13; *see also Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003) (explaining that claim terms “are examined through the viewing glass of a person skilled in the art”). The Defendants contend that “[t]he ordinary and customary meaning of the phrase ‘amine polymer’ is simply a polymer having at least one repeating unit that contains an amine group.” (Defs.’ Opening Br. at 6.) Genzyme counters that the term “amine polymer” has “no clearly established meaning and requires context in order to define.” (Pl.’s Opening Br. at 7; Defs.’ Ex. F, Meijer Tr., at 54:1-8.) Notably, at no point does Genzyme assert that the ordinary and customary meaning of the term “amine polymer” is a polymer in which each repeating unit contains an amine group.

Despite Genzyme’s assertion that the term “amine polymer” has no clearly established meaning, it does not dispute that the words “amine” and “polymer,” standing alone, have readily identifiable ordinary and customary meanings in the field. Indeed, both parties agree that the ordinary and customary meaning of the term “polymer” is that of a large molecule composed of repeating units, and they further agree that “amine” is understood to refer to a nitrogen-based compound. Consequently, the most natural reading of the term “amine polymer” would seem to be a polymer containing nitrogen-based amine, which accords with Defendants’ construction of the disputed term.³ Yet I recognize, as do both parties, that claim terms must be construed in

³ Of course, a patentee is free to become his own lexicographer and attach “a specific definition . . . to a claim term,” *Phillips*, 415 F.3d at 1316, but any such definition must be “clearly stated in the patent specification or file history,” *Vitronics*, 90 F.3d at 1580; *see also CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (noting that a disputed claim term will not receive a special definition unless “the patentee acted as his own

light of the entire intrinsic record, including the specification and prosecution history.

Accordingly, I now turn to this evidence to determine the proper claim construction.

B. Patent Specification

Although the claim language “provides the metes and bounds of the right which the patent confers on the patentee,” *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999), patent claims do not stand alone and “must be read in view of the specification of which they are a part,” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995) [*Markman I*]. Indeed, the specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics*, 90 F.3d at 1582; *see also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004) (“In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention.”). A district court must bear in mind, however, the critical distinction between “using the specification to interpret the meaning of a claim, which is permissible, and importing limitations from the specification into the claim, which is not.” *Id.* at 1323 (internal quotations and citations omitted). For example, many patent specifications contain descriptions

lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history”). The Federal Circuit has recently reiterated that even if a preferred embodiment in a patent illustrates a special definition of a term, this is not enough to redefine the term if the specification “does not clearly contain such a special definition.” *Laryngeal Mask Co. Ltd. v. Ambu A/S*, 618 F.3d 1367, 1372 (Fed. Cir. 2010). In this case, although embodiments contained in the ’775 Patent depict molecules with amine groups in each structural unit, it is undisputed that this requirement is not “clearly stated in the patent specification or file history.” Accordingly, Genzyme has not become its own lexicographer and has not specially defined “amine polymer” as a molecule containing an amine group in each and every repeating structural unit. I do not, however, rest my decision on this basis given the clear evidence in the patent specification, discussed below. I merely note that although Genzyme could have avoided this claim construction dispute by specifically defining the term “amine polymer” in the patent, it failed to do so.

of specific embodiments or examples of the patented product, and while “possible embodiments of the invention may throw light on the meaning” of a disputed claims term, *Nazomi Commc’ns*, 403 F.3d at 1369, the Federal Circuit has “repeatedly warned against confining the claims to those embodiments,” *Phillips*, 415 F.3d at 1323. Indeed, even where a specification and its detailed embodiments “repeatedly” imply a specific limitation on a claim, “[t]his is not enough . . . to limit the patentee’s clear, broader claims.” *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1347 (Fed. Cir. 2009). Ultimately, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Phillips*, 415 F.3d at 1316.

An analysis of the ’775 Patent’s specification supports Defendants’ construction of the disputed claim term in two key respects. First, the specification discloses nine embodiments of the patented product, each of which is described as a polymer “characterized by a repeating unit having the formula [of an amine monomer] *or a copolymer thereof*.” (’775 Patent, at 2:50-4:67 (emphasis added.)) The inclusion of the term “copolymer” indicates that although the embodiment may be composed only of the repeating units containing an amine group, it may also be composed of repeating units containing an amine group *and some other repeating unit*. Yet as Defendants point out and Genzyme does not deny, the patent specification “does not impose any requirements on the chemical structure of the other repeating unit(s), and thus there is no requirement that the other repeating unit(s) contain an amine group.” (Defs.’ Opening Br. at 7.) Accordingly, the patent specification seems to contemplate a copolymer that conforms to Defendants’ proposed construction of the term “amine polymer”: namely, a polymer in which one or more, but not necessarily all, of the repeating structural units contain an amine group.

Genzyme counters that the meaning of the phrase “or a copolymer thereof” is altered when read in the context of the patent specification, which discloses only two specific embodiments of copolymers, each of which contains an amine group in each structural unit. (’775 Patent, at 3:15-45, 3:58-4:16.) Genzyme argues that these examples constitute a “clear teaching” that an “amine polymer” must contain an amine group in every structural unit. (Pl.’s Responsive Br. at 3.) As noted above, however, the Federal Circuit has “repeatedly warned against confining the claims to those embodiments” contained in the specification, and Genzyme’s argument falls into the trap of “importing limitations from the specification into the claim, which is not [permitted].” *Phillips*, 415 F.3d at 1323.

The Federal Circuit’s recent decision in *Kara Technology Inc. v. Stamps.com Inc.*, 582 F.3d 1341 (Fed. Cir. 2009), illustrates this principle. In that case, the parties disputed whether the term “security indicia” required the use of an encrypted “key” embedded into electronic data. *Id.* at 1346. The court acknowledged that “the specification repeatedly discusses a key embedded in the preestablished data” and that every detailed embodiment disclosed in the patent included such a key. *Id.* at 1347. Yet the court held that because “none of the claims at issue on appeal recite the term ‘key,’” the repeated reference to “keys” in the embodiments was “not enough . . . to limit the patentee’s clear, broader claims.” *Id.* The court explained that it “will not limit [a patentee] to his preferred embodiment” because “[t]he claims, not specification embodiments, define the scope of patent protection.” *Id.* at 1348. Similarly, although the specific embodiments in the ’775 Patent describe copolymers with an amine group in each structural unit, the actual claim language recites no such requirement. Thus, just as in *Kara Technology*, the scope of Claim 22 should not be limited to a narrower preferred embodiment.

To read such a limitation into the claim would be to “import[] limitations from the specification into the claim, which is not [permitted].” *Phillips*, 415 F.3d at 1323.

In addition to the inclusion of the phrase “or a copolymer thereof,” the specification also incorporates a “Table 1” listing “candidate polymers” that were tested by Genzyme for their phosphate-binding effectiveness. (’775 Patent, at 6:20-49.) One of these polymers, poly(trimethylammoniomethyl styrene chloride) (referred to herein as “PTSC”), is a copolymer composed of two different monomers. One of these monomers contains an amine group, but the other, divinyl benzene, does not contain any amine group or ammonia derivative. (*Id.* at 15:39-41.) Thus, the resulting copolymer does not contain an amine group in each repeating structural unit, which again is consistent with Defendants’ construction of the term “amine polymer.” In light of the Federal Circuit’s statement that it “normally [does] not interpret claim terms in a way that excludes disclosed examples in the specification,” *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007), the reference to PTSC in Table 1 of the specification provides further support for Defendants’ construction of the term “amine polymer.”⁴

Genzyme responds that PTSC is not representative of the class of “amine polymers” covered by Claim 22 and that its inclusion in Table 1 of the specification should therefore be ignored. (Pl.’s Responsive Br. at 4.) In particular, Genzyme points out that while both parties agree that Claim 22 covers polymers that are “aliphatic,” or non-aromatic, (Pl.’s Ex. C, Amended

⁴ Similarly, the specification also states that the “polymers are preferably crosslinked” by adding a crosslinking agent during or after polymerization. (’775 Patent, at 5:9-11.) The specification then discloses a lengthy list of suitable crosslinking agents, (*id.* at 5:12-16), none of which contain an amine group. The combination of these crosslinking agents with the disclosed amine monomers will again form copolymers in which some, but not all, of the structural units contain an amine group. Defendants reason that, like the inclusion of PTSC in Table 1 of the specification, the reference to these crosslinking agents supports their position that “amine polymers” need not contain an amine group in each structural unit.

Joint Statement, at 3), the divinyl benzene contained in PTSC makes it aromatic.⁵ Accordingly, Genzyme argues that PTSC is disqualified from the class of “amine polymers” covered by Claim 22, yet it struggles to explain why, if PTSC is not protected by Claim 22, it is nevertheless listed in the specification as a “candidate polymer. (’775 Patent, at 6:38.) Indeed, Genzyme’s briefings provide no explanation for the inclusion of PTSC in the patent specification, and at oral argument Plaintiff’s counsel surmised only that PTSC was included because it had been involved at some stage of developmental testing. Yet whatever the case may be, Genzyme cannot escape the fact that the ’775 Patent specification clearly describes PTSC, a polymer with amine groups in only *some* repeating units, as a “candidate polymer” for its invention. This fact, in addition to the specification’s coverage of monomers containing amine groups “or copolymers thereof,” serves as further intrinsic evidence that the proper construction of the term “amine polymer” is a molecule in which one or more repeating units contains an amine group.

In an effort to counter this evidence favoring Defendants’ construction of the disputed term, Genzyme includes several citations of its own to the patent specification, but the passages cited are unpersuasive. For example, Genzyme points out that the specification states that the patent relates to a class of polymers with “improved phosphate binding properties” that function by “ion exchange.” (’775 Patent, at 2:2-6.) Genzyme argues that based on this description, a person of ordinary skill in the art would infer “that it is the amine in these polymers that is responsible for binding the phosphate.” (Pl.’s Opening Br. at 7-8.) This argument is unconvincing. As an initial matter, Genzyme produces no evidence, aside from extrinsic evidence in the form of testimony from its hired expert, to support the proposition that a person in the field would draw the inference that the amine in a polymer is chiefly responsible for

⁵ In this context, the term “aromatic” refers not to a particular smell, but rather to the presence of a chemical compound characterized by a “benzene ring” structure.

phosphate binding. (*See* Meijer Decl., ¶ 29.) More importantly, however, even accepting the premise that a person in the field would recognize that amine is responsible for binding phosphate, this does not suggest that *each and every* monomer of a molecule must have an amine group in order to be considered an “amine polymer.” Indeed, if it is understood that it is the amine which possesses therapeutic value, it could just as easily be assumed that as long as a polymer contains amine in at least *some* of its repeating units, it will function as an “amine polymer.”

Genzyme also argues that the specification shows that the most effective phosphate-binding polymers have an amine group in every repeating structural unit and that a person in the field would therefore understand “amine polymer” to mean a molecule in which every monomer contains an amine group. (Pl.’s Opening Br. at 9.) First, Claim 22 does not state that an “amine polymer” must be one of the “most effective” phosphate binding molecules, and so Genzyme’s argument once again improperly imports a limitation from the specification that is not present in the claim language. Moreover, as a factual matter, Defendants point out that Table 1 of the patent specification shows that some polymers that have an amine group in every repeating unit are actually *less* effective at phosphate binding than other polymers with amine groups in only some monomers. (*See* ’775 Patent, at 6:31-38 [indicating that poly(allyltrimethylammonium chloride), which has an amine group in each repeating unit, has a phosphate binding efficacy of 0.3 meq/g, while PTSC, which does not have an amine group in each repeating unit, has an efficacy of 0.7 meq/g].) Accordingly, this argument is also unpersuasive.

In light of the repeated use of the phrase “or a copolymer thereof” to describe “amine polymers” and the prominent inclusion of PTSC in Table 1, the intrinsic evidence contained in the specification clearly supports Defendants’ construction of the disputed claim term. This is

especially significant given the Federal Circuit's direction that the specification is "the single best guide to the meaning of a disputed term," *Vitronics*, 90 F.3d at 1582. Nonetheless, the specification is not necessarily determinative of a claim construction dispute, and therefore the analysis does not end here.

C. Prosecution History of Patent

In addition to the claim language and the patent specification, a court deciding a claim construction dispute "should also consider the patent's prosecution history." *Markman I*, 52 F.3d at 980. A patent's prosecution history "consists of the complete record of the proceedings before the PTO" and assists a district court in its claims construction inquiry because "the prosecution history was created by the patentee in attempting to explain and obtain the patent." *Phillips*, 415 F.3d at 1317. Nevertheless, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.*

The prosecution history of the '775 Patent also favors Defendants' construction of the term "amine polymer." Specifically, in a 1996 response to an enablement rejection of its patent application by the USPTO,⁶ Genzyme defined the invention covered by the '775 Patent as a polymer that "includes *a* repeat unit having either a basic nitrogen atom or a cationic ammonium nitrogen atom." (Defs.' Ex. E, Resp. to Enablement Rejection, at 4 (emphasis added.)) This definition of an amine polymer as a molecule that "includes *a* repeat unit" with an amine group

⁶ 35 U.S.C. § 112 requires that an inventor applying for a patent must "set forth in a patent specification sufficient information to enable a person skilled in the relevant art to make and use the invention." 3-7 Chisum on Patents § 7.03. Unless corrected in a responsive filing, failure to make an adequate enabling disclosure will result in the PTO rejecting a patent application.

supports Defendants' contention that an "amine polymer" must contain at least one ("a") monomer with an amine group but need not contain amine in every repeating unit.

Genzyme contends that this history is irrelevant because it "concerns claims not in issue in this litigation."⁷ (Pl.'s Responsive Br. at 4.) Yet even if the prosecution history concerns other claims, this does not make the history irrelevant because the Federal Circuit has explained that the relevant prosecution history encompasses "the complete record of the proceedings before the PTO." *Phillips*, 415 F.3d at 1317; *cf. Kara Technology*, 582 F.3d at 1347 (looking to the language of other claims not at issue in the litigation in order to interpret a disputed claim term). Recognizing this, Plaintiff's counsel attempted at oral argument to downplay the significance of this file history by arguing that the cited passage refers to "polymers" in general and not "amine polymers" in particular. It is clear from context, however, that the "polymers" referred to in the PTO filing are the same "amine polymers" described in the '775 Patent, as the PTO filing describes them as "ion exchange polymers" that "possess an affinity for phosphate."⁸ (Defs.' Ex. E, Resp. to Enablement Rejection, at 4.) Alternatively, Genzyme falls back on the argument that the cited prosecution history "does not suggest that the polymers in claim 22 could consist of repeating units that do not contain an amine group" because a person of ordinary skill in the art would know that amine provides therapeutic value and would therefore infer that every repeating unit contains an amine group. (Pl.'s Responsive Br. at 4-5.) As already discussed above, this argument is unconvincing.

⁷ The statement in the 1996 response to the enablement rejection does refer to claim 22, (Resp. to Enablement Rejection, at 4), but Plaintiff's counsel explained at oral argument that the "claim 22" described in the 1996 filing is different than the "claim 22" contained in the final version of the '775 Patent approved a year later.

⁸ Indeed, Genzyme's own expert testified that the functionality of a polymer—in particular, its phosphate binding efficiency—is an essential part of what makes it an "amine polymer." (Defs.' Ex. F, Meijer Tr., at 94:23-95:12.)

D. Expert Opinions and Other Extrinsic Evidence

Extrinsic evidence, such as expert testimony or a dictionary definition, is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004). In particular, expert opinions are less helpful than intrinsic evidence because “extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Phillips*, 415 F.3d at 1318. And while expert testimony may be helpful to the extent that it “provide[s] background on the technology at issue” or “establish[es] that a particular term . . . has a particular meaning in the pertinent field,” an expert’s conclusory assertion as to the meaning of a claim term or opinion that contradicts the weight of the intrinsic evidence is not useful and will not be considered. *Phillips*, 415 F.3d at 1318. When a party offers expert testimony in a claim construction dispute, “the court has complete discretion to adopt the expert legal opinion as its own, to find guidance from it, or to ignore it entirely, or even to exclude it.” *Markman I*, 52 F.3d at 983.

Defendants have not offered expert opinion at this time, but Genzyme has presented testimony from Dr. Egbert Meijer in support of its construction. Dr. Meijer explained certain technical aspects of the patented invention, including the process of synthesizing crosslinked polymers and the structure of specific copolymers identified in the patent specification. (Meijer Tr., at 90:8-93:17; 79:7-81:4.) Dr. Meijer also opined that the term “amine polymer” does not have an established meaning in the field but that, based on his own reading of the patent, he understood it to refer to a polymer with an amine group in each repeating unit. (Defs.’ Ex. F, Meijer Tr., at 54:1-8, 81:9-13.) To the extent that Dr. Meijer’s testimony is instructive as to the understanding of certain technical terms in the field, I have taken his testimony into account, and

relevant parts of this testimony have already been referenced above. Yet to the extent that Dr. Meijer offers a personal view on the ultimate meaning of the disputed claim term “amine polymer,” such conclusory assertions are not entitled to deference, especially when they conflict with the clear weight of the intrinsic evidence. Accordingly, although Dr. Meijer’s testimony is helpful in explaining certain technical aspects of the ’775 Patent, in the face of countervailing intrinsic evidence his personal views on the meaning of the disputed claim term ultimately do little to support Genzyme’s proposed construction.

E. Miscellaneous Arguments

Genzyme also raises two additional arguments in support of its construction of “amine polymer,” but neither is persuasive. First, Genzyme asserts that the Defendants’ proposed construction of “amine polymer” is incorrect because it would embrace “polymers comprised of multiple non-amine repeating units that do not contribute to phosphate binding, as well as repeating amine units that only constitute a very small proportion of the whole.” (Pl.’s Opening Br. at 9.) This broad construction, Genzyme maintains, runs “counter to the very therapeutic purpose” of the invention and is unduly over-inclusive. (*Id.*) Such an argument fails for two reasons. First, in construing claim terms a district court must look to the intrinsic evidence contained in the patent itself, not to an abstract notion of the “therapeutic purpose” of the invention. *See Vitronics Corp. v. Conceptronic*, 90 F.3d at 1582 (“[T]he court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and . . . the prosecution history.”). Second, to the extent, if any, that Defendants’ proposed construction is over-inclusive, Genzyme’s construction presents a parallel problem in its under-inclusiveness. That is, while Defendants’ proposed construction would classify a polymer as an “amine polymer” even if it contains only a small number of monomers with amine groups,

Genzyme's proposed construction would deny that a polymer is an "amine polymer" even if 99 percent of its structural units contain amine groups. And while each proposed construction faces this same definitional dilemma, only one interpretation—that proposed by Defendants—"stays true to the claim language and most naturally aligns with the patent's description of the invention." *Phillips*, 415 F.3d at 1316.

Genzyme also raises a linguistic challenge to Defendants' proposed construction based on the effect of the term "aliphatic" in claim 22, but the argument is too attenuated to be convincing. Genzyme observes that in a joint claim construction statement the parties agreed that the word "aliphatic" refers to "a molecule that . . . is non-aromatic." (Pl.'s Responsive Br. at 4.) On the basis of this fact, Genzyme assumes: (1) that this means every individual structural unit in the molecule must be non-aromatic; (2) that the word "amine" modifies the term "polymer" in the same way as does the word "aliphatic"; and (3) that this must mean that every structural unit of a polymer covered by claim 22 contains an amine group. (*Id.*) The first of these assumptions is questionable, however, because the parties' agreement as to the meaning of "aliphatic" extends only to the molecular level and does not reach the level of specificity of individual repeating units. That is, just because the parties agree that a *molecule* is non-aromatic does not necessarily mean that they agree that each and every *repeating unit* must be non-aromatic.⁹ The second of Genzyme's assumptions is also flawed because Genzyme provides no

⁹ Consider the example of a large polymer in which 99 percent of the repeating units are non-aromatic and only one percent are aromatic. Because the parties' joint construction of the term "aliphatic" does not specify that every individual structural unit must be non-aromatic, reasonable minds can differ as to whether this polymer should be deemed a "non-aromatic" on an overall molecular level. Nor does this seem to be a purely hypothetical concern. I note that in the Joint Claim Construction Statement submitted by the parties, Genzyme initially construed the term "aliphatic" to refer to a molecule that "does not contain aromatic groups," while Defendants construed it more generally to mean a molecule that "is non-aromatic." (Pl.'s Ex. B, Joint Statement, at 3.) But in a subsequent Amended Joint Claim Construction Statement, the parties

support for its theory that the words “aliphatic” and “amine” modify the term “polymer” in the same way. Indeed, Genzyme spends a significant portion of its brief arguing that although the individual word “amine” has a well-established meaning, it takes on a different and uncertain meaning when construed as part of the phrase “amine polymer.” As Genzyme does not make such an argument about the word “aliphatic,” it seems that “amine” and “aliphatic” do *not* modify the term “polymer” in the same manner. Because these first two premises of Genzyme’s syllogism are flawed, the conclusion likewise is doubtful. But in any case, the term “aliphatic” pertains to a completely different claim limitation not at issue in this dispute. Accordingly, its relevance to the meaning of the term “amine polymer,” if any, is minimal.

III. CONCLUSION

The clear weight of the intrinsic evidence, as seen in the patent specification and prosecution history, favors the Defendants’ construction of the disputed claim term. Additionally, Genzyme’s various secondary arguments are unpersuasive. Accordingly, as proposed by Defendants, I adopt the following construction of the term “amine polymer” as used in the ’775 Patent: a molecule that is capable of interacting with a polar solvent; is non-aromatic; contains cross-links; and is composed of repeating units, one or more of which contains an amine group.

Date: February 1, 2011

_____/s/
J. Frederick Motz
United States District Judge

agreed to Defendants’ interpretation of “aliphatic” as simply a molecule that “is non-aromatic,” thereby stopping short of defining the term on a monomer-specific level. (Pl.’s Ex. C, Am. Joint Statement, at 3.) The point is this: if the word “aliphatic” does not apply on a monomer-specific level, then it is of no use in determining whether the word “amine” applies to each and every repeating unit in a polymer.